

### REMARKS

The present communication responds to the Office Action of December 16, 2004. In the Office Action Summary, the Examiner indicated that claims 1-27 were withdrawn from consideration while claims 28-75 were allowed. Pages 2-5 of the Office Action, however, detail rejections of claims 28-75. Thus, the applicants assume that the Examiner intended to reject claims 28-75. For the reasons set forth below, the rejections are traversed and reconsideration is respectfully requested.

The claimed invention is an apparatus for subcutaneous administration of an injectable product, wherein the apparatus comprises a needle protection sleeve and an indicator which indicates to a user, during insertion of a needle for injection, that the sleeve is in a certain position. It is respectfully submitted that this is not disclosed or taught by the cited references.

#### Rejection under 35 U.S.C. § 102

Claims 55, 59-69, 72-75 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,674,203 to Lewandowski or U.S. Patent No. 6,547,764 to Larsen et al. This rejection is traversed at least for the following reasons.

#### *Lewandowski*

The Examiner asserts that the Lewandowski et al. reference discloses each of the elements recited in claims 55, 59-69 and 72-75 including an indicator 55/51/38/84 (as with the Office Action dated June 4, 2004, the Examiner appears to have mistakenly referred to element 83 as element 38) which “indicates to a user that a needle protection sleeve is in its distal position.” The Examiner states: “An indicator, which is visibly [sic], indicates to the user of the apparatus.” However, as noted in the response filed September 22, 2004, the Examiner does not explain what the indicator of Lewandowski et al. visibly indicates to the user of the apparatus. The applicants respectfully submit that, at least, Lewandowski does not disclose an indicator which indicates to the user of the apparatus that the needle protection sleeve is in the distal position during insertion of the injection needle, for example during injection or administration of the injectable product.

While Lewandowski et al. describe an indicator, the indicator is a safety indicator for visibly indicating when a needle guard is not locked in the extended position. *Lewandowski et al., column 4, lines 62-64*. As noted above, the Examiner does not set forth any interpretation of what is indicated by the Lewandowski indicator. The applicants thus assume that the Examiner agrees with the statements set forth in the response filed September 22, 2004 regarding the safety indicator of Lewandowski. In contrast to the indicator of Lewandowski, the indicator of the present invention indicates retraction of the needle protection sleeve – or that the needle protection is in the distal position during insertion of a needle for injection.

The indicator of the Lewandowski et al. reference does not indicate the position of the needle guard, it indicates whether the needle guard is locked. Thus, for example, the indicator may indicate that the needle guard is not locked although it is in an extended position. Likewise, the indicator may indicate that the needle guard is not locked when it is in a non-extended position. Lewandowski et al. do not teach or suggest an indicator for indicating that a needle protection sleeve has attained its distal position during insertion of a needle for injection.

In response to the applicant's arguments set forth in the response filed September 22, 2004, the Examiner argues:

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., indicator to indicate the position of the needle guard) are not recited in the rejected claim(s). *December 16, 2004 Office Action, Page 4*.

The applicants respectfully submit that the feature indicated by the Examiner (an indicator to indicate the position of the needle guard) is, in fact, recited in each of the independent claims. The applicants respectfully draw the Examiner's attention to the following previously presented elements of the independent claims (emphasis added):

(claim 28.) *an indicator which indicates to the user of the apparatus, during insertion of the needle, that the needle protection sleeve is in the distal position, the indicator comprising a circuit, the circuit being positionable between an open position and a closed position, one of the closed position or the open position indicating that the needle protection sleeve is in the distal position.*

(claim 46.) an electric circuit ... wherein the electric circuit forms *an indicator which indicates* to the user of the apparatus, during insertion of the needle, *that the needle protection sleeve is in the distal position*.

(claim 55.) *an indicator which visibly indicates* to the user of the apparatus *that the needle protection sleeve is in the distal position* during insertion of the injection needle for administration of the injectable product.

(claim 64.) *an indicator which indicates* to the user *that the needle protection sleeve is in the distal position*, the indicator being formed as a marking that is visible when the needle protection sleeve is in the distal position during insertion of the injection needle for administration of the injectable product but is substantially not visible when the needle protection sleeve is not in the distal position.

(claim 66.) *an indicator that audibly indicates* to the user *that the needle protection sleeve is in the distal position* during insertion of the needle for administration of the injectable product.

(claim 67.) *an active indicator for signaling* to the user *that the needle protection sleeve is in the distal position* during insertion of the injection needle for administration of the injectable product.

Thus, the applicants again submit that each of the independent claims recite an indicator indicating that a needle protection sleeve has attained its distal position during insertion of a needle, for example for administration or injection of a product. As this is not shown by Lewandowski and as each of the remaining claims depend from these claims, it is respectfully submitted that the presently pending claims are patentable over the Lewandowski et al. reference. Accordingly, it is respectfully requested that the rejection of claims 55, 59-69, 72-75 as anticipated by Lewandowski et al. be withdrawn.

*Larsen et al.*

The Examiner also asserts that the Larsen et al. reference discloses each of the elements recited in claims 55, 59-69 and 72-75. Specifically, the Examiner asserts that Larsen et al. (at Col. 11, line 45-60 and in claim 1) discloses an indicator which indicates to a user that a needle protection sleeve is in its distal position. Further, the Examiner states: "An indicator, which is visibly [sic], indicates to the user of the apparatus." However, the Examiner does not explain what the indicator of Larsen et al. visibly indicates to the user of the apparatus. The applicants respectfully submit that, at least, Larsen does not disclose an indicator which indicates to the user

of the apparatus that the needle protection sleeve is in the distal position during insertion of the injection needle, for example during injection or administration of the injectable product.

Larsen et al. teach an indicator for indicating when an injection needle has been used:

In order to provide the user with a clear visible indication that the injection needle has been used, the safety shield 10 can be provided with at least one transparent area 32 ...When the injection needle is in the initial position ready to be inserted into the human body, the projection 22 is located in the first part 27 of the track 18. In this position the first area 33 on the outside surface of the hub 4 is visible through the transparent area 32 of the safety shield 10. After the injection, the projection 22 is located in the hole or well 31, and the transparent area 32 of the safety shield 10 is dislocated such that the second area 34 is now visible through the transparent area. *Larsen et al., column 11, lines 48-50, lines 66-67 and column 12, lines 1-7.*

Larsen et al. explain that the indicator indicates that the injection needle has been used and that the needle protector is in a position protecting the needle so that it can be safely removed. Thus, Larsen et al. disclose an indicator for indicating that the needle has been used and is safely protected for disposal. As noted above, the Examiner does not set forth any interpretation of what is indicated by the Larsen indicator. The applicants thus assume that the Examiner agrees with the statements set forth in the response filed September 22, 2004 regarding the indicator of Larsen.

The indicator of Larsen et al. is not an indicator which indicates to the user of the apparatus that the needle protection sleeve is in the distal position during insertion of the injection needle during insertion of a needle for an injection or administration of an injectable product. As explained above, each of the independent claims recite an indicator indicating that a needle protection sleeve has attained its distal position during insertion of the injection needle, for example for administration or injection of an injectable product. Each of the remaining claims depend from these claims. It is thus respectfully submitted that the pending claims are patentable over the Larsen et al. reference. Accordingly, it is respectfully requested that the rejection of claims 55, 59-69, 72-75 as anticipated by Larsen et al. be withdrawn.

Rejection under 35 U.S.C. § 103

Claims 28-54, 56-58, 70-71 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,674,203 to Lewandowski and further in view of U.S. Patent No. 6,287,283 to Ljunggreen et al or U.S. Patent Publication No. 2002/0002344A1 to Douglas.

In the rejection, the Examiner states: “Both Lewandowski and Hjertman indicator’s [sic] are manual apparatus [sic] for the movement of the needle and the indicator positioning of the needle.” Without addressing the accuracy of this statement, the applicants note that Hjertman is not being relied upon in the rejection and, thus, the applicants will not address the disclosure of Hjertman.

As discussed above, Lewandowski et al. does not teach or disclose an indicator indicating that a needle protection sleeve has attained its distal position during insertion of a needle, for example for injection or administration of an injectable product. Neither Ljunggreen et al. nor Douglas et al. teach this and, therefore, even if proper, the asserted combinations would not make the claimed invention obvious.

*Ljunggreen et al.*

The Ljunggreen et al. reference discloses an apparatus for the registration of the setting of a medical device, the setting of which implies a mechanical adjustment of at least two relatively moveable elements of the device. The object of the Ljunggreen et al. invention is to provide an apparatus for a more safe detecting of the setting of the medical device, for example, of the dosage measured for insulin administration. Thus, a further object is to provide a more safe reading of the pharmaceutical dosage given from a dosage unit. *See Ljunggreen et al., column 1, lines 50-55.* Ljunggreen et al. thus disclose a dosage indicator. Ljunggreen et al. does not teach or suggest indicating the position of a needle protection sleeve during insertion of a needle for injection or administration of an injectable product.

*Douglas et al.*

The Douglas et al. reference discloses lancing devices and methods for obtaining samples of blood and other fluids from the body for analysis or processing. *Douglas et al., paragraph*

[0002]. One of the objects of the invention of the Douglas et al. reference is “to ensure that a sufficiently large drop of body fluid is developed at an incision, and that the body fluid reaches a test strip.” *Douglas et al., paragraph [0020]*. Douglas et al. thus disclose a drop sensing mechanism. Douglas et al. does not teach or suggest indicating the position of a needle protection sleeve during insertion of a needle for injection or administration of an injectable product.

Thus, even if one skilled in the art were to consider the combined teaching of the combination proposed by the Examiner, the result would not produce an insertion apparatus for the administration or injection of an injectable product including an indicator that shows that a needle protection sleeve has attained a certain position during insertion of the needle for injection or administration of the product.

As each of the independent claims recite an indicator indicating that a needle protection sleeve has attained its distal position during insertion of a needle, for example for injection or administration of an injectable product, and as each of remaining claims depend from these claims, it is respectfully submitted that the pending claims are not taught by the asserted combinations. Accordingly, it is respectfully requested that the rejection of 28-54, 56-58, 70-71 under 35 U.S.C. § 103(a) be withdrawn.

No new claim fees have been generated by this Amendment. However, Applicant submits herewith a petition for a three month extension of time along with a check in the amount of \$1020.00 to cover the fee associated with the petition. The Commissioner is also hereby authorized to charge any deficiencies and credit any overpayments associated with this paper or the petition to Deposit Account No. 04-1420.

Conclusion

This application is in allowable form, and reconsideration and allowance are respectfully requested.

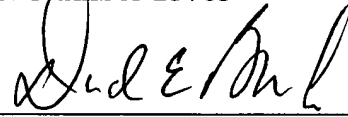
Respectfully submitted,

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Date: \_\_\_\_\_

*June 16, 2005*

By: \_\_\_\_\_



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